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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/955,657

09/18/2001

Richard E. Wooley

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07/01/2005

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,657

Applicant(s)

WOOLEY ET AL.

Examiner

Micah-Paul Young

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-15,18-22 and 56-62 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,2,5-15,18-22 and 56-62 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Acknowledgment of Papers Received: Remarks and Amendment dated 4/6/05.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1,2, 5-15, 18-22 and 56-62 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Raad et al (USPN 5,688,516 hereafter '516 and USPN 6,165,484 hereafter '484) and Kruse et al (USPN 5,646,151 hereafter '151). The claims are drawn to a method of treating a bacterial infection by applying a composition consisting of a chelating agent, antimicrobial agent and carrier.

1. The '516 patent discloses a method of treating Gram positive and negative bacterial infections by applying a composition of chelating agents such as EDTA and triethylene tetramine dihydrochloride and various anti-bacterial agents including oxytetracycline (col. 4, lin. 31 – 53; col. 5, lin. 37-53). The '151 patent discloses topical formulations comprising chelating agents such as EDTA and antibiotic agents such as neomycin, amikacin and tetracyclines (col.33, lin. 3-38; col. 34, lin. 25-48; col. 41, lin. 59-col. 43, lin. 54). The reference establishes the knowledge in the art of combining chelating agents and antibiotic/fungal agents in order to treat skin injuries

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topically. A skilled artisan would be motivated to include the chelating agents and antibiotics of '516 into the formulation of '151 in order to treat a wider range of bacterial infections.

4. Regarding claims 18-20 drawn to various skin injuries, the references disclose various well-known antibacterial/fungal agents, which are well known in the treatment of skin injuries.

Though the references are silent to an ulcer specifically, it is the position of the examiner that the combination of chelators and biocides disclosed in the prior art would be sufficient in treating a bacterial infection wherever it would arise. It is the position of the examiner that these limitations do not impart patentability on the claims, barring a showing of criticality to the type of injury sustained. The examiner invites applicant to provide evidence of a criticality to the type of injury. Until such time, the claims will remain obviated by the prior art.

5. With these things in mind one of ordinary skill in the art would have been motivated to follow the teachings of the '151 reference by treating infections with topical formulation comprising chelators. It would be well within the level of skill in the art to substitute and/or combine the any number of active ingredients in the formulation of '151, which teaches topical systemic treatment of infections, with the active components taught by '516, particularly with formulation comprising chelating agents. The '516 patent provides guidance to specific bacterial strains that can be treated by specific formulation and would provide further motivation for combination in order to treat a wider variety of infections. In all an artisan of ordinary skill would have been motivated to include the chelators and active agents of '516 into the various formulations of '151 in order to treat infections, as suggested by '516. It would have been obvious to combine these teachings and suggestions with an expected result of a topical antibacterial formulation.

Response to Arguments

6. Applicant's arguments filed 4/6/05 have been fully considered but they are not persuasive. Applicant argues that:

a. There is no motivation to combine the teachings of '484, '516 and '151.

7. Regarding this argument, applicant has amended the claims to more specifically recite the treatment of bacterial infections in the broader claims. However, the combination of '516 and '151 still reads on such a treatment. The '151 teaches a topical treatment formulation comprising chelators and antibacterial agents. The '516 patent teaches a similar formulation for treating bacterial infections. It would be obvious to combine the actives of '516 into a topical formulation as taught in '151 for treatment of infections, since both reference are within the same field of endeavor.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MP Young

Micah-Paul Young
Examiner
Art Unit 1618



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600